IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
SOUTHERN DIVISION

GENUS LIFESCIENCES, INC., 514 N. 12th Street, Allentown, PA 18102, Plaintiff, v. U.S. FOOD AND DRUG ADMINISTRATION, 10903 New Hampshire Ave. Silver Spring, MD 20993, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, 200 Independence Ave., S.W. Washington, D.C. 20201, ALEX AZAR, *In His Official Capacity as Secretary of Health and Human Services,* U.S. Department of Health and Human Services 200 Independence Ave., S.W. Washington, D.C. 20201, STEPHEN HAHN, M.D., *In His Official Capacity as Commissioner of the United States Food and Drug Administration*, 10903 New Hampshire Ave. Silver Spring, MD 20993, Defendants.	Civil Action No. **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

COMPLAINT

Congress directed the U.S. Food and Drug Administration to withdraw a drug's approval if the application for approval is found to have contained "any untrue statement of a material fact." 21 U.S.C. § 355(e)(5). Plaintiff Genus Lifesciences, Inc. brings this action for declaratory and injunctive relief to require FDA to comply with that statutory duty.

An application for a new drug ("NDA") must include a Chemistry, Manufacturing, and Controls ("CMC") section identifying the facilities where the drug will be manufactured and providing data that is specific to those facilities. Such statements in the CMC section are undoubtedly material to FDA's review of the application, as FDA cannot approve the application without determining that the facilities, equipment, and systems in place are adequate to ensure that the drug will be safe and effective. *See* 21 U.S.C. § 355(d)(3) (the applicant must demonstrate, among other things, that "the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are [a]dequate to preserve its identity, strength, quality, and purity"). For example, to demonstrate that the facility can adequately manufacture the drug in question, the applicant must manufacture three batches of the drug ("Exhibit Batches") at the facility, and data concerning the Exhibit Batches (including 12 months of long-term stability data) must be included in the CMC section of the application.

If an applicant makes an untrue statement to FDA about where a drug will be manufactured and provides data from the wrong facility, then FDA cannot properly perform its legally mandated evaluation, as the agency will be focused on the wrong

facility and the wrong CMC data. Consequently, if FDA learns that an approved application contained an untrue statement about where the drug would be manufactured, then § 355(e)(5) requires FDA to withdraw its approval of the application.

Lannett Company made just such a material untrue statement in its application to manufacture and market Numbrino®, a cocaine-based anesthetic. Lannett's application stated that the drug would be manufactured in a facility in Cody, Wyoming, and the application contained data specific to that facility (*e.g.*, data related to the Exhibit Batches that were manufactured in the Cody facility). In reality, Lannett shuttered that facility while its application was pending and moved its manufacturing operations to a different facility in Carmel, New York. Lannett's CMC section thus presented FDA with data about the wrong facility—one that was closed and where Lannett had no intention of manufacturing the drug—and failed to provide critical data about the facility where Lannett actually intended to manufacture Numbrino®.

Lannett even declined a golden opportunity to correct its misstatements: Months before the agency approved its application, Lannett reconfirmed to FDA that it would manufacture Numbrino® exclusively in Cody and that the Cody manufacturing facilities were "active" and "ready for inspection." Just days later, Lannett told investors that it had "ceased operations at the Cody plant" and was "already produc[ing]" Numbrino® at a different facility in New York. Lannett no doubt understood that if it corrected the false statements while its application was

still pending, FDA would have required it to amend its application to provide additional data about the facility where Numbrino® would really be manufactured, including 12 months of stability data from three Exhibit Batches manufactured in the New York facility. As explained below, that would have significantly delayed FDA's approval of Lannett's application.

Genus brought these material, untrue statements to FDA's attention nine months ago, but FDA has refused to take the legally required action to initiate proceedings to withdraw Lannett's approval. Federal law does not allow FDA to turn a blind eye to material, untrue statements in approved NDAs. Genus thus files this lawsuit to compel agency action unlawfully withheld and unreasonably delayed. *See* 5 U.S.C. § 706(1).

NATURE OF THE ACTION

1. This is an action for declaratory and injunctive relief arising from the defendants' failure to take required action under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301–392, in violation of the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 551–555, 706. Specifically, this action seeks redress for the defendants' failure to perform their nondiscretionary duty to initiate proceedings to withdraw approval of the Numbrino® NDA (No. 209575).

JURISDICTION AND VENUE

2. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. § 1331 because this action arises under the laws of the United States.

3. Venue is proper in this District pursuant to 28 U.S.C. § 1391(e) and 5 U.S.C. § 703 because this is a civil action in which one of the defendants is an officer or agency of the United States that resides in this judicial District.

4. There is currently an actual, justiciable controversy between the parties concerning whether FDA's refusal to initiate withdrawal proceedings on Lannett's NDA is consistent with the requirements of the FDCA and the APA.

PARTIES

5. Plaintiff Genus is a specialty pharmaceutical company with its principal place of business at 514 N. 12th Street, Allentown, PA 18102. Genus manufactures Goprelto®, a cocaine-based anesthetic approved by FDA in December 2017.

6. Defendant FDA, which has its principal office at 10903 New Hampshire Avenue, Silver Spring, Maryland 20993, is a federal agency headquartered in Maryland. It regulates prescription drugs under authority granted by Congress and delegated by the Secretary of Health and Human Services.

7. Defendant Stephen Hahn, M.D., is being sued in his official capacity as Commissioner of FDA. As Commissioner, Dr. Hahn has responsibility for the activities of FDA, including the actions complained of here. Dr. Hahn maintains an office at 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

8. Defendant U.S. Department of Health and Human Services, which has its principal office at 200 Independence Avenue SW, Washington, D.C. 20201, is a federal agency headquartered in the District of Columbia. It has authority over FDA.

9. Defendant Alex Azar is being sued in his official capacity as Secretary of Health and Human Services. As Secretary, Mr. Azar has responsibility for the activities of the Department of Health and Human Services, including the actions complained of herein. Secretary Azar maintains an office at 200 Independence Avenue SW, Washington, D.C. 20201.

STATUTORY AND REGULATORY FRAMEWORK

Manufacturing Standards and Pre-Approval Inspections for New Drug Approval

10. Under the FDCA, any person seeking to introduce a new drug into interstate commerce must obtain FDA's approval. *See* 21 U.S.C. § 355(a).

11. A company seeking FDA's approval to market a new brand-name drug not previously approved must submit a New Drug Application ("NDA"). An NDA must include, among other things, full reports of investigations of the drug's safety and effectiveness. *See* 21 U.S.C. § 355(b)(1).

12. An NDA applicant must demonstrate, among other things, that "the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of [the] drug are [a]dequate to preserve its identity, strength, quality, and purity." 21 U.S.C. § 355(d)(3). As explained below, a critical part of meeting that requirement is identifying the facility or facilities where the drug will be manufactured so that FDA can review the CMC section containing data from those facilities and, if necessary, inspect those facilities.

13. To secure approval of an NDA, drug companies must comply with a rigorous set of application requirements aimed at ensuring the safety and efficacy of

the proposed new drug. One set of requirements seeks to ensure that the drug company's quality systems conform to FDA's stringent current good manufacturing practices ("CGMP") regulations (which establish quality standards for, among other things, facilities, production and process controls, equipment, and personnel) set forth in parts 211, 225, and 226 of Chapter 21 of the Code of Federal Regulations. 21 C.F.R. § 210.1(a); *see also* FDA, Guidance for Industry, Quality Systems Approach to Pharmaceutical CGMP Regulations 1 (2006), https://www.fda.gov/media/71023/download (noting that a manufacturer's quality systems must comply with CGMP regulations to ensure that the drug product is safe and effective).

14. To enable FDA to evaluate whether an applicant's quality systems are adequate to ensure the drug's identity, strength, quality, and purity, *see* 21 U.S.C. § 355(d), NDAs are required to contain a CMC section describing the facilities, controls, and processes that will be used to manufacture the new drug, *see* 21 U.S.C. § 355(b); *see also* 21 C.F.R. § 314.50(d)(1). Among other things, the CMC section must contain detailed information about both the "drug substance" (*i.e.*, the active ingredient) and the "drug product" (*i.e.*, the finished product).

15. For the drug substance, the CMC section must include (or reference a Drug Master File that includes) detailed information about the structure and general properties of the drug substance and validated analytical procedures for determining whether the substance meets the necessary specifications. The CMC section must also include, among other things, a detailed description of the manufacturing process and process controls used at the manufacturing facility, including controls of raw

materials used in the manufacturing process and controls of critical steps and intermediates. *See generally* FDA, Comprehensive Table of Contents Headings and Hierarchy, https://www.fda.gov/media/76444/download.

16. For the drug product, the CMC section must include a detailed description of the finished drug product and its components. It must also include, among other things, a detailed description of the steps in the manufacturing process—including the specific pieces of equipment used during each manufacturing step—and of the process controls used at the manufacturing facility, including controls for excipients (*i.e.*, inactive ingredients) used in the manufacturing process and controls for critical steps and intermediates. The CMC section must also include a detailed analysis of three Exhibit Batches manufactured by the applicant, including 6 months of accelerated stability data and 12 months of long-term stability data from the Exhibit Batches. *See generally id.*

17. Since the CMC data is uniquely tied to the facility in which it was generated, the CMC section of the NDA must provide the name and address of each facility that will be involved in the manufacturing, processing, packaging, labeling, and testing (including in-process, release, and stability testing) of both the drug substance and the drug product. 21 C.F.R. § 314.50(d)(1)(i)–(ii).

18. FDA uses a program of "Pre-Approval Facility Evaluations and Inspections" to ensure "that any manufacturing facility named in the application is capable of manufacturing the drug in conformance to Current Good Manufacturing Practice (CGMP) requirements and that the data submitted in the application are

accurate and complete." FDA, Integration of FDA Facility Evaluation and Inspection Program for Human Drugs: A Concept of Operations 2 (2017), https://www.fda.gov/media/107225/download.

19. After an NDA is submitted, FDA reviews the data in the CMC section and conducts a Pre-Approval Facility Evaluation to determine whether FDA should physically inspect the facility before approving the application. The evaluation "considers available information about each facility named in [the] application, the drug being manufactured, and other information." *Id.* FDA also performs a "facility risk assessment" that considers, among other things, the facility's inspection and performance history. *Id.* at 3. In determining whether an inspection is necessary, the agency considers (1) the risks associated with the new drug product and the manufacturing process and facilities; and (2) the existence of inaccurate or unreliable information in the NDA. *See* FDA, *Chapter 46—New Drug Evaluation*, *in* Compliance Program 9–10 (2019), https://www.fda.gov/media/121512/download.

20. Depending on the results of the initial evaluation, FDA may conduct a Pre-Approval Inspection of any manufacturing facility named in the application. In conducting that inspection, FDA officials typically visit the facility to evaluate its compliance with CGMP regulations. Their objectives include assessing whether the facility contains sufficient equipment, personnel, and quality controls to operate on a commercial scale, evaluating whether the facility's actual manufacturing processes conform to the manufacturing description from the NDA, and auditing the facility's raw data for accuracy and reliability. *See id.* at 14.

21. After the Pre-Approval Inspection, the FDA investigators who performed the evaluation report their observations. Investigators typically report discrepancies between information in the NDA and what the investigators observed at the facility with regard to manufacturing processes, inaccurate or unreliable data, and other examples of nonconformance with current good manufacturing practice regulations. *See id.* at 24–25. The Pre-Approval Inspection team is also responsible for writing a "narrative" evaluation summarizing its observations. *See id.* at 25.

22. If FDA finds that the manufacturing facilities or protocols are "inadequate to preserve [the] identity, strength, quality, and purity" of the new drug, it must "issue an order refusing to approve the application." 21 U.S.C. § 355(d); 21 C.F.R. § 314.125.

Changing an Identified Manufacturing Facility in an NDA Before Approval Requires New Submissions and FDA Approval

23. FDA permits an applicant to amend its NDA while the NDA is pending before the agency. 21 C.F.R. § 314.60(a). Filing an amendment typically extends the amount of time needed for FDA's review. *See id.* § 314.60(b).

24. An amendment that contains "[a] substantial amount of new data or new information not previously submitted to, or reviewed by, the FDA" is considered a "major amendment" and typically delays FDA's decision on approval for several months. FDA Ctr. for Drug Evaluation & Research, *NDAs and BLAs: Communication to Applicants of Planned Review Timeliness, in* Manual of Policies and Procedures 4–5 (2014), https://www.fda.gov/media/72710/download; *see* 21 C.F.R. § 314.60(b)(1).

25. If an applicant closes a manufacturing facility that has been identified in a *pending* NDA as the facility where the drug will be manufactured, the applicant must submit an amendment identifying the facility where the drug will actually be manufactured, and it must provide new chemistry, manufacturing, and controls information for that facility. *See* 21 C.F.R. § 314.50(d)(1)(i).

26. The amendment should include, among other information, data from three exhibit batches of the drug produced at the new manufacturing site. In particular, it should include *twelve months* of long-term stability data and *six months* of "accelerated" stability data (i.e., data gathered under conditions designed to increase the rate of degradation of the product) from those exhibit batches. *See* FDA, Guidance for Industry, Q1A(R2) Stability Testing of New Drug Substances and Products 10–11 (2003), https://www.fda.gov/media/71707/download.

27. The amendment should also include revised labeling identifying the correct manufacturing facility for the drug. *See* 21 C.F.R. § 314.50(c)(2)(i); *see also id.* § 201.1(a) ("A drug or drug product . . . in finished package form is misbranded under section 502(a) and (b)(1) of the act if its label does not bear conspicuously the name and place of business of the manufacturer, packer, or distributor.").

Withdrawal of Approval for Untrue Statements of Material Fact

28. If an NDA contains an untrue statement about the facility where the drug will be manufactured, the applicant does not amend the NDA to correct that statement, and FDA subsequently approves the application, then FDA *must* withdraw the approval upon learning of the untrue statement.

29. The FDCA provides that the "Secretary *shall*, after due notice and opportunity for a hearing to the applicant, withdraw approval of an [NDA] if the Secretary finds . . . that the application contains *any* untrue statement of a material fact." 21 U.S.C. § 355(e) (emphases added); *see* 21 C.F.R. § 314.150(a)(2)(iv).

30. An untrue statement is material if it "has a 'natural tendency to influence, or is capable of influencing,'" FDA's decision to approve or disapprove the application. *Neder v. United States*, 527 U.S. 1, 16 (1999) (quoting *United States v. Gaudin*, 515 U.S. 506, 509 (1995)).

31. An untrue statement in an NDA that misidentifies the facility where a drug will be manufactured is obviously capable of influencing FDA's decision to approve the application. Indeed, as explained above, an applicant's providing accurate information in the CMC section of an application, thus facilitating FDA's review and (if necessary) inspection of the identified manufacturing facilities, is a critical part of the approval process.

32. In addition to withdrawing approval that has already been granted, FDA "will refuse to approve" a pending application that "contains an untrue statement of a material fact." 21 C.F.R. § 314.125(a)(7). And, pursuant to longstanding FDA policy, FDA ordinarily will require the applicant to submit "a new application" and to have its president or CEO certify the "truthfulness and accuracy" of that new application. FDA, CPG Section 120.100 — Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities (1991), https://www.fda.gov/

regulatory-information/search-fda-guidance-documents/cpg-sec-120100-fraud-untrue-statements-material-facts-bribery-and-illegal-gratuities.

GENERAL ALLEGATIONS

33. As explained in detail below, Lannett's[1] application to FDA for approval to market Numbrino® contained the following material, untrue statements regarding the facilities that would be used to commercialize Numbrino® upon approval:

- The drug substance and drug product would be manufactured at a facility located at 601 Yellowstone Avenue in Cody, Wyoming (the "Cody Yellowstone Facility").
- The drug substance raw materials would be held and tested at a facility located at 119 Road 2AB in Cody, Wyoming (the "Cody 119 Facility").
- A facility located in Carmel, New York (the "Carmel Facility") would be used only for drug substance release testing, for drug product and stability release testing, and for excipients and packaging components release testing.

34. These statements were untrue because, contrary to its express representations to FDA, Lannett publicly stated throughout the summer and fall of 2019 that it had:

- Ceased operations at the Cody Yellowstone Facility and the Cody 119 Facility;
- Laid off virtually all the employees at both the Cody Yellowstone Facility and the Cody 119 Facility;
- Sold the equipment from the Cody facilities;
- Leased the Cody 119 Facility to a shoe manufacturer; and

[1] In 2007, Lannett acquired Cody Laboratories, Inc. *See* Ex. A. For simplicity's sake, references to "Lannett" in this complaint include Lannett's wholly owned subsidiary, Cody Laboratories.

- Moved drug product manufacturing to the Carmel Facility.

Lannett's Application Represents that Numbrino® Will Be Manufactured at a Facility in Cody, Wyoming

35. In December 2008, Lannett began manufacturing, without FDA approval, a nasal anesthetic containing cocaine hydrochloride as an active ingredient. Lannett manufactured the unapproved drug at the Cody Yellowstone Facility.

36. In September 2017, Lannett sent FDA a new drug application for its cocaine hydrochloride anesthetic, Numbrino®, under 21 U.S.C. § 355(b)(2). On information and belief, the CMC section of Lannett's application identified the Cody Yellowstone Facility as the only facility where Numbrino® would be manufactured.

37. FDA accepted Lannett's application for review in November 2017. The following month, in December 2017, FDA performed a Pre-Approval Inspection of the Cody Yellowstone Facility as part of its review of the Numbrino® NDA. *See* Ex. B.

38. In July 2018, FDA issued a complete response letter for the Numbrino® NDA, indicating that the application would not be approved in its present form and requiring Lannett to resubmit its application. Lannett responded on June 21, 2019.

Lannett Shuts Down the Cody Facilities and Moves Production to New York While Its Application Is Pending, But Does Not Inform FDA

39. Apparently unknown to FDA, Lannett began planning to close the Cody facility at least 18 months before FDA approved the Numbrino® application, and it completely shut down the facility roughly five months before FDA announced its approval.

40. On June 11, 2019, with its Numbrino® NDA still pending, Lannett disclosed in an SEC filing that it had decided "to sell the equipment and real estate

utilized by the Cody API business and to have Cody Labs cease all operations." The company stated that the restructuring would result in "a reduction of all remaining 70 positions at Cody Labs" and would "be substantially completed by September 30, 2019." Ex. C at 2.

41. On June 12–16, 2019, various Wyoming news sources reported that Lannett's Cody Labs facility in Cody, Wyoming was being shut down and 80 people were being laid off. *See, e.g.*, Ex. D (Cody Enterprise); Ex. E (Yellowstone Gate); Ex. F (Powell Tribune); Ex. G (Powell Tribune); Ex. H (Wyoming Daily).

42. In August 2019, Lannett's CEO, Tim Crew, stated on an earnings conference call that in July, Lannett had "completed" its "previously announced cost reduction plan" by "ceasing … operations at CODY" and "selling the associated equipment." He also stated that Lannett intended to manufacture Numbrino, not at the Cody Yellowstone Facility as it had told FDA, but instead at the Carmel Facility. Ex. I at 2.

43. In September 2019, Lannett sold its manufacturing equipment from the Cody Yellowstone Facility at an online auction site, *see* Ex. J, and shut down its Codylabs.com website, *see* Ex. K.

44. Also in September 2019, a local newspaper ran a story on the fact that "Cody Laboratories, maker of controlled substances, is shut down for good." The article reported that Robert Jaffe, a Lannett spokesperson, "confirmed Cody Labs equipment has been sold and the company is in the process of selling its real estate." Ex. L (Gillette News Record).

45. A property listing for the lease of the Cody Yellowstone Facility states that Cody Labs ceased manufacturing operations in October 2019. Ex. M.

46. In another earnings call in November 2019, Lannett's CEO confirmed that Lannett had "ceased operations at the Cody plant" and relocated its manufacturing operations to the Carmel Facility. Ex. N at 2.

47. By December 2019, a local newspaper reported that Lannett had leased the Cody 119 Facility to Kanye West's shoe and apparel business, Adidas Yeezy, which planned to use it to develop and manufacture footwear. *See* Ex. O (Powell Tribune).

Lannett Passes Up a Golden Opportunity To Correct the Material Untrue Statements in Its Numbrino® Application

48. On October 31, 2019—months after Lannett shut down its Cody operations—FDA sent Lannett an information request regarding the Numbrino® application. The request stated that FDA was "reviewing the CMC section of [Lannett's] submission," noted that the CMC section did not include certain required information, and asked Lannett to update its submission "to ensure complete facility information is provided for all facilities used for commercial production." Ex. P.

49. Through the information request, FDA simultaneously (1) reminded Lannett of its obligation to keep its application up to date with truthful and accurate information about the facilities that would be used for commercial production of Numbrino®, and (2) provided Lannett with a golden opportunity to correct the untrue statements in its application before the application was approved.

50. Lannett, however, did not take advantage of that opportunity. Instead, on November 1, 2019, Lannett submitted an updated Form 356h to FDA for the sole purpose of updating the facility information in the CMC section of the Numbrino® NDA. In this submission, Lannett continued to identify the Cody Yellowstone Facility and the Cody 119 Facility as the locations of commercial manufacturing and raw material testing. *See* Ex. Q.

51. Specifically, Lannett represented that the shuttered Cody Yellowstone Facility would be used for, among other things, "Drug substance manufacturing" and "Drug product manufacturing," *id.* at 2, and that the shuttered Cody 119 Facility would be used for "receipt and sampling of drug substance raw materials," *id.* at 4. Lannett represented that both Cody facilities were "active" and "ready for inspection." *Id.* at 2, 4. Lannett knew that these statements were untrue, as it had already closed the Cody facilities.

52. Lannett identified the Carmel Facility as one of several "active" facilities that would perform "release and stability testing." *Id.* at 5–6. But it did not tell FDA that Numbrino® would be *manufactured* at the Carmel Facility (and thus that the CMC section that FDA was relying on was not the correct CMC section), even though Lannett's CEO had said as much to investors months earlier (*see* ¶ 42, *supra*).

53. By signing the November 1, 2019 submission, Lannett certified that all the statements therein were "true and accurate" and acknowledged that making a willfully false statement in the submission would be a criminal offense under 18 U.S.C. § 1001. Ex. Q at 3.

54. Lannett may have withheld the truth from FDA in order to avoid delaying FDA's processing of Lannett's application. If Lannett had told FDA in November 2019 that it planned to manufacture Numbrino® at the Carmel Facility instead of the Cody Yellowstone Facility, FDA could have conducted a Pre-Approval Inspection of the Carmel Facility. *See* ¶¶ 18–21, *supra*. FDA also would have required Lannett to submit a complete CMC section for the Carmel Facility, including 12 months of long-term stability data and 6 months of accelerated data for three batches of Numbrino® produced at the Carmel Facility, which Lannett had not yet generated. *See* ¶ 26, *supra*. Had Lannett been truthful, it would have needed to wait over a year to gather that data and then file a major amendment to its application (which would have started a new 6-month review cycle for the application), resulting in a lengthy delay (approximately 21 months) before FDA could approve the application.

55. Whatever Lannett's motives, the fact is that it did not tell FDA the truth about the shuttering of the Cody facilities. Instead, just five days after assuring FDA that Numbrino® would be manufactured in Cody and that the Cody facilities were "active" and "ready for inspection," Lannett's CEO told investors that Lannett had "ceased operations at the Cody plant," that it had "already produced [Numbrino®] at our Carmel facility," and that it would "complete the technical transfer at the New York site" *after* FDA approved the company's (now materially false) application. Ex. N at 2.

FDA Approves Numbrino® While Unaware of Lannett's Materially Untrue Statements

56. On January 10, 2020, FDA approved Lannett's Numbrino® application.

57. The FDA-approved label for Numbrino® identified Cody Laboratories in Cody, Wyoming as the site where Numbrino® would be manufactured. *See* Ex. R at 19. FDA would not have approved the label in this form if it had known that the Cody facilities were no longer in operation and Lannett had no plans to manufacture Numbrino® there.

58. Less than a month later, on February 5, 2020, Lannett's CEO stated in a quarterly earnings call that the company was producing Numbrino® at the Carmel Facility and expected to "ship the product shortly." Ex. S at 4.

FDA Fails To Address
Lannett's Material Misstatement

59. FDA is aware that Lannett's designation of the Cody Yellowstone Facility as the manufacturing site for Numbrino®, its designation of the Cody 119 Facility as the site where drug substance raw materials would be held and tested, and its designation of the Carmel Facility as a site that would be used only for release testing and not for product manufacturing, were untrue statements of material fact in the Numbrino® NDA, as Genus submitted letters to FDA in February and March 2020 specifically alerting FDA to Lannett's untrue statements and reminding FDA of its statutory obligation to initiate proceedings to withdraw Lannett's approval.

60. Specifically, on February 11, 2020, Genus alerted FDA to SEC filings and news reports showing that Lannett had "closed the manufacturing site identified in the [Numbrino®] NDA (and inspected by FDA in December 2017) and transferred the product to another facility in Carmel, New York months before the NDA was approved." Ex. T at 3–4. Genus pointed out that FDA was likely unaware of the

closure of the Cody facilities, as "had it known it would have required Cody/Lannett to amend its NDA to include the new manufacturing site (and related CMC data associated with the new site) and … would likely have required an inspection of the new manufacturing site." *Id.* at 3. FDA did not respond to this letter.

61. On March 18, 2020, Genus wrote to FDA again. Once again, Genus directed FDA to publicly available sources—including SEC filings, earnings call transcripts, and news reports—demonstrating that "while Cody/Lannett represented to FDA that it intended to manufacture Numbrino® at the Cody, Wyoming facility, it simultaneously made contradictory public statements indicating that it had, in fact, closed [that] facility." Ex. U at 3–4. Genus also reminded FDA of its "mandatory and nondiscretionary" duty under the FDCA to withdraw approval of Numbrino® if Lannett's application contained an untrue statement of material fact. *Id.* at 2. FDA did not respond to this letter either.

62. On June 30, 2020, having heard nothing from FDA, Genus notified the agency that it was preparing to file this lawsuit and asked for a meeting to discuss the matter. FDA agreed to a meeting, and on August 13, 2020, Genus discussed this issue with several senior FDA officials via teleconference. In that meeting, Genus voiced its frustration at FDA's continued failure to take any steps toward withdrawing Lannett's approval. It advised FDA that if the agency did not take action, it would have no choice but to file this lawsuit.

63. FDA has never disputed that Lannett's Numbrino® application contained untrue statements of material fact. Yet nine months after Genus first

brought this matter to the agency's attention, and three months after Genus's meeting with senior FDA officials, FDA has not taken any public steps toward withdrawing its approval of Numbrino®; nor has it told Genus that it has any intention of doing so. The agency's prolonged failure to act has thus left Genus with no reasonable choice but to file this lawsuit.

FDA's Failure To Act Will Harm Genus and Expose Patients to Potentially Unsafe or Ineffective Drugs

64. The defendants' refusal to withdraw Lannett's approval will cause serious harm to Genus while exposing patients to potentially unsafe or ineffective drugs manufactured at an undisclosed facility for which Lannett provided materially false information in the CMC section of its application.

65. Genus's Goprelto® and Lannett's Numbrino® are the only two FDA-approved drugs that use cocaine hydrochloride as an active ingredient. They are both indicated for the induction of local anesthesia of the mucous membranes when performing diagnostic procedures and surgeries on or through the nasal cavities in adults. If FDA persists in its unlawful refusal to withdraw Lannett's approval and allows Lannett to continue distributing Numbrino®, Genus will suffer a loss of market share, resulting in significant financial harm.

66. Not only will FDA's refusal to take the legally required action harm Genus, it also will endanger public health and safety by exposing Americans to a potentially unsafe or ineffective drug made in a facility about which Lannett provided materially false information in the CMC section of its application. By doing so, Lannett deprived FDA of the opportunity to review an accurate CMC section and to

decide, based on that information, whether to approve Lannett's application and whether to inspect the facility prior to approval to ensure that it could manufacture Numbrino® safely and properly.

67. Congress recognized the importance of manufacturing facilities and controls, and the data generated from the manufacturing facility, to the safety and efficacy of drugs. It thus required FDA, before approving an NDA, to evaluate the "methods used in, and the facilities and controls used for, the manufacture, processing, and packing of" a drug to ensure they are adequate to "preserve [the drug's] identity, strength, quality, and purity." 21 U.S.C. § 355(d). FDA cannot perform that statutorily required analysis if an applicant is not truthful about where the drug will be manufactured and does not provide an accurate CMC section and accurate data about that facility.

68. In this case, FDA determined that to fulfill its statutory duty, it needed to conduct a Pre-Approval Inspection of the facility where Lannett had told it that Numbrino® would be manufactured. FDA thus inspected the now-shuttered facility in Cody, Wyoming in December 2017, two years before the Numbrino® approval. Lannett's materially untrue statements deprived FDA of the opportunity to conduct a similar, Numbrino®-focused pre-approval inspection of the facility in Carmel, New York where Lannett actually manufactures Numbrino®. They also deprived FDA of the opportunity to review an accurate CMC section for the Carmel Facility, including (among numerous other pieces of data described above) the required stability data on three exhibit batches of Numbrino® produced in that facility. In short, Lannett's

CMC section was inaccurate and incomplete and could not have supported filing or approval of Lannett's application.

69. Numbrino® is likely to be used by thousands of individuals as an anesthetic for nasal cavity surgeries. Because Lannett's untrue statements interfered with FDA's ability to evaluate the "methods used in, and the facilities and controls used for, the manufacture, processing, and packing of" Numbrino®, 21 U.S.C. § 355(d), it is impossible to know whether Numbrino® is safe and effective.

CLAIM FOR RELIEF
(Declaratory and Injunctive Relief)

Violation of the Administrative Procedure Act and Federal Food, Drug, and Cosmetic Act (Action Unlawfully Withheld and Unreasonably Delayed)

70. Genus realleges and incorporates by reference the allegations set forth in paragraphs 1 through 69 of this Complaint as if fully set forth herein.

71. The APA directs courts to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1).

72. The FDCA provides, in no uncertain terms, that FDA "shall, after due notice and opportunity for hearing to the applicant, withdraw approval . . . if the Secretary finds . . . that the application contains any untrue statement of a material fact." 21 U.S.C. § 355(e).

73. This directive is "unambiguously binding": "[T]he ordinary meaning of 'shall' is 'must,'" and similarly worded provisions in the FDCA have been held to "impose[] mandatory duties upon the agency charged with its enforcement." *Cook v. FDA*, 733 F.3d 1, 7, 12 (D.C. Cir. 2013) (discussing 21 U.S.C. § 381(a)).

74. Lannett's application for Numbrino® stated that the drug substance and finished drug product would be manufactured, and the drug substance raw materials held and tested, at facilities in Cody, Wyoming, and not at a facility in Carmel, New York. Those statements were untrue: Lannett closed the Cody facilities and relocated its manufacturing operations to New York long before FDA approved the Numbrino® application.

75. Lannett's untrue statements are material. FDA is required by statute to evaluate the facility in which a drug will be manufactured, its manufacturing controls, and the associated CMC section in the application, as part of FDA's assessment of whether the application provides adequate assurance that the drug will be safe and effective. FDA cannot perform that legally required evaluation if it is focused on the wrong facility.

76. FDA is aware of Lannett's material untrue statements. FDA's refusal to take steps to withdraw its approval of Lannett's NDA violates the FDCA and the APA.

REQUEST FOR RELIEF

Genus requests that the Court grant the following relief:

A. Enter an order declaring that FDA has unlawfully withheld and unreasonably delayed taking legally required action to withdraw approval of Lannett's Numbrino® NDA.

B. Enter an order compelling FDA to immediately initiate proceedings to withdraw approval of Lannett's Numbrino® NDA.

C. Provide such other relief as the Court deems appropriate.

Respectfully submitted,

Dated: November 12, 2020

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